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EUROPE'S REACH:

A NEW CHAPTER IN INTERNATIONAL CHEMICALS LAW

by Marcos A. Orellana*

INTRODUCTION

For almost a decade, the deliberative bodies and Member States of the European Union have been developing a new legal framework to govern the marketing and trade of chemicals. When adopted, the proposed regulation on Registration, Evaluation, and Authorization of Chemicals ("REACH") will mark a fundamental change in the way chemicals are managed in Europe and around the world. This REACH reform process was driven by the recognition that the existing patchwork of EU law on chemicals was inadequate to securing a healthy environment for present and future generations. REACH was coined in the EU Commission's 2001 White Paper, but it builds on years of European experience combating regional pollution in the Baltic, the North Sea, the Mediterranean, the Rhine, the Danube, and elsewhere. It now stands as the EU's plan for meeting the global 2020 goal to minimize the health and environmental impacts of chemicals agreed by the governments of the world at the World Summit on Sustainable Development in Johannesburg in 2002.

This White Paper's high-minded proposal triggered a complex process within the Commission to draft the legislative text that was ultimately proposed in 2003. Economic concerns about the competitiveness of the EU chemicals industry, as well as the workability and transaction costs of proposed arrangements, led EU institutions to scale back on the grander vision of REACH. Very heavy lobbying by the chemical industry and some prominent countries outside the EU forced concessions on the scope of REACH, the duty of care, minimum data requirements, and the consideration of alternatives.¹ Intense debate within the European Parliament and the Council has produced two critical texts that supersede the Commission's drafts: the result of the Parliament's first reading vote; and the political agreement among the 25 Member States (the Common Position). At the time of writing, the parliament was preparing to take up the Council's agreed text and consider amendments in the second reading vote.

Despite the political influences, REACH is still guided by some important principles. For the first time REACH places the burden of proof on chemical makers and importers to demonstrate the safety of their products, rather than relying on authorities to prove them dangerous. REACH will generate valuable data about the properties and uses of several thousand chemicals and mixtures, which will be available to downstream customers and the public. REACH may drive adoption of safer substitutes or the generation of inherently greener solutions, especially if the Parliament's first reading vote prevails in the final political deal. Many countries outside Europe will feel the ripple effects

of REACH through global supply chains and evolving international standards. Developing countries may benefit from safer products from the EU and access to new markets for products not requiring registration.

This article provides an international legal perspective on REACH. Since REACH is still under debate in the European Parliament and the Council, this piece addresses the basic contours of the likely political agreement expected in 2006, with a special focus on the relevance of human rights and trade law. After tracing the origins of REACH, this article explores the role of the main EU institutions involved in the development of the regulation. Next, this article looks at the core elements of REACH, focusing on objectives, principles, requirements, and impacts. An examination of some of the trade-related issues debated at the World Trade Organization ("WTO") sheds light on a possible trade challenge against REACH.

ROOTS OF THE PROBLEM: PIECEMEAL APPROACHES TO CHEMICALS MANAGEMENT

Over the course of many years, European authorities, elected officials, industry, and civil society have concluded that the existing EU legal framework for chemicals is unable to provide adequate information about the impact of many chemicals on human health and the environment. They are not alone. The national chemical laws developed in the 1970s and later, both inside and outside the EU, are antiquated and ineffective. At the turn of the 21st Century the EU had managed to fully assess approximately 140 chemicals; this nearly three decades under a web of directives on chemical labeling, transport, and restrictions. Current EU law distinguishes between "new" chemicals and "existing" chemicals. Existing chemicals were on the market before September 1981 numbering more than 100,000 substances and over 99 percent of commercial chemicals in terms of tonnage.² While existing EU Directives require that new substances are tested and their risks assessed, "existing" substances are not subject to the same testing requirements. As a result, EU law has not obtained basic screening data about the characteristics and impacts of most chemicals. Without such information, chemicals policy is blind to the risks posed by chemicals and frozen into inaction.³

In addition to the general lack of knowledge about the properties and the uses of existing substances, current EU law on chemicals suffers from other serious deficiencies. The duty to

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provide credible information about chemical safety falls on authorities instead of the enterprises that make and sell chemicals. The risk assessment process is slow and costly, allowing continued production, marketing, and use of potentially dangerous chemicals. Further, the Commission is responsible for carrying out risk assessments and adequate cost/benefit analysis prior to any regulatory proposal relating to marketing and use of dangerous substances.⁴ Liability regimes are insufficient to ensure redress for injured parties when cause and effect are distanced and if adequate data on the effects of chemicals are not available. Finally, the EU's current legal framework on chemicals is a patchwork of Directives and Regulations that has been characterized as a barrier to innovation by discouraging research and favoring existing substances over new, safer chemicals.

The European Union is home to the 500 billion Euro chemicals industry, the world's largest. As the source of a third of global chemical production, and with an educated and environmentally aware citizenry, Europe is at the center of the contemporary struggle to reconcile its industrial economy with protection of public health and the environment. How REACH is ultimately agreed and how it is implemented will have important implications for the direction of international law and the evolving role of the EU as a leader internationally on matters of health and environmental protection.

REACH'S BACKGROUND: EVOLUTION OF EU CHEMICALS POLICY AND EU INSTITUTIONS

A comprehensive narrative of the EU's reform of its chemicals framework would require extensive detail on the unprecedented and intense involvement of national governments, industry, and civil society in a broad debate handled largely by EU Institutions. Fortunately, up to 2004 that narrative can be found elsewhere.⁵ This section provides a general overview of key events and actors, with a view to contextualizing the international law dimensions of REACH.

THE EVOLUTION OF EU CHEMICALS POLICY AND REGIONAL AGREEMENTS

In the late 1960s, at a time of increased environmental awareness, the first signs of what would later become a patchwork legislation concerning chemicals began to surface. The first EC legislative instrument on industrial chemicals was the 1967 Directive on Classification and Labelling of Chemicals,⁶ which focused on harmonizing trade in chemicals and protecting workers from acute exposure, but did not require testing or other data. Subsequently, the 1976 Directive on Restrictions of Certain Substances⁷ was an attempt to harmonize chemicals pol-

icy in response to trade obstacles resulting from some Members banning or restricting production or use of certain chemicals. Under this Directive, the Commission committed itself to carrying out risk assessments and cost/benefit analyses prior to any proposal or adoption of a regulatory measure concerning chemicals. In 1979, an important amendment to the 1967 Directive was adopted, establishing the "new" and "existing" distinction.⁸ In 1988, the Council replaced several directives concerning preparations with the Directive on Classification and Labelling on Preparations.⁹

By 1993, disparities in the national legislations implementing the above-mentioned Directives and their impact on EC trade, coupled with increasing awareness of the substantial threat posed to human health and the environment by chemicals,

led to the 1993 Council Regulation on Evaluation of Existing Substances. According to this regulation, certain categories of data were to be provided to the authorities. Progress on risk assessment was slow, however, and restrictions or bans could only be adopted if the authority could show strong evidence of the substance's negative effects. This business-as-usual approach ultimately proved unacceptable to countries particularly affected by persistent pollution.

Meanwhile, regional agreements were concluded to address pollution issues. Nordic and

other countries such as Belgium, the Netherlands, the United Kingdom, and Germany have taken a lead in efforts to protect the marine environment of the North Sea, for example, including the phase-out of hazardous chemicals. The North Sea Conferences have produced political commitments which have played an important role in influencing legally binding environmental management decisions both nationally and within the framework of competent international bodies. The 1995 Ministerial Declaration adopted in Esbjerg, Denmark stands as a landmark in that it defines an operational objective: to cease all releases to the marine environment of human-made and natural hazardous substances, in order to achieve background levels of natural hazardous substances by 2020 (in one generation).¹⁰ Similar wording was adopted in June 2001 by the EU Council to define the objectives of the new EU chemicals strategy and by the 2006 Strategic Approach to International Chemicals Management, adopted under the auspices of the United Nations Environment Programme.¹¹

This objective was also adopted by the 1992 Convention for the Protection of the Marine Environment of the North-East Atlantic (the "OSPAR Convention") in its first meeting in Sintra, Portugal in 1998.¹² A review of its first five years experience in implementing activities to achieve the "one genera-

REACH will ensure a common playing field within the EC internal market, where all chemical producers and traders will be subject to the same specific requirements.

tion” goal led to the 2003 Hazardous Waste Strategy, which ultimately aims to achieve “concentrations in the marine environment near background values for naturally occurring substances and close to zero for manmade synthetic substances” by the year 2020.¹³ In order to achieve this objective, the OSPAR Convention actively engaged EU institutions, contributing its expertise to the EU chemicals policy reform process.

EU INSTITUTIONS AND THE POLITICAL BATTLE OVER REACH

Against this broader international legal background, in 1998 environment ministers of EU Member States initiated intensive public dialogue about chemicals, public health, and the environment. In an informal meeting in Chester, UK, the environment ministers concluded that a comprehensive review of the system was necessary, with a view to introducing principles of sustainable development in the chemicals sector. The Commission conducted this review in 1998, identifying major weaknesses in the current chemicals legislation. The Council welcomed the Commission’s progress and requested it to organize a brain-storming meeting open to all relevant stakeholders that could inform a proposal. In February 2001, the Commission presented its White Paper on a Strategy for a Future Chemicals Policy (REACH), a prescient nickname for one of the hardest fought political battles in Brussels. All this led to an enormously contentious and complex political debate with unprecedented participation by NGOs, business, and others.

As the administrative branch of the EU, the European Commission has particular responsibilities in preparing legislation proposals.¹⁴ In the ambit of REACH, DG-Environment and DG-Enterprise were tasked to draft REACH together. The Commission has attempted an inclusive process of debate to address the complex issues associated with chemicals policy. In 2001, for example, after presenting its White Paper, the Commission organized a stakeholder conference and convened technical working groups. In May 2003, the entire draft regulation was posted on the internet for consultation, which enabled unprecedented participation by governments, industry, and a range of civil society. On October 29, 2003, the Commission sent its proposed REACH regulation to the Parliament. Since then, the Commission has been actively involved in consultation with Council and Parliament, and also managing a range of implementation projects with authorities, industry, and others.

The European Parliament is the elected political body of the EU, with a key role in the co-legislation process. Its Members (“MEPs”) are elected in national elections and they are organized by political groups.¹⁵ While the Parliament had a role during the discussion of the White Paper, when after the draft entered

Parliament, it became the focus of intense committee debate (2003-2005). The Environment Committee took the lead, in what turned out to be a hard fought turf battle, and other committees gave “opinions.” On November 17, 2005, Parliament adopted over one thousand amendments to the draft in its first reading vote. The Parliament has subsequently been involved in dialogue with Council on the draft, and is expected to hold a second reading vote in 2006.

The Council of the European Union represents the (now 25) Member States of the European Union and organizes its work on the basis of specialized topics, e.g. Environment Council, Competitiveness Council, etc.¹⁶ This arrangement means that the Council reflects national political influence, but is also informed by technical experts from ministries, competent authorities, etc. This arrangement has also had profound influence on the Council’s stance before REACH. In fact, while early discussions on chemicals policy were steered by the Environment Council, the draft REACH regulation was placed

under the competence of the Competitiveness Council, which led to greater emphasis on issues of workability, innovation, and implementation costs. The Council also operates under the leadership of a presidency that sets the agenda on a rotating six-month basis. This has had implications for REACH process, as key decisions were made under the Italian, Dutch, and other presidencies. In December 2005 the Council reached a preliminary

political agreement under the UK Presidency. After regular deliberations on most major aspect of the 2003 draft regulation, and after the 2005 preliminary political agreement, in February 2006 the Council adopted its “common position” regarding the Parliament’s first reading vote, which essentially defines the practical bounds for an eventual compromise.¹⁷ Any remaining differences between the Council and Parliament’s second reading vote would be resolved through a formal conciliation process. REACH is now expected to enter into force in 2007.

REACH IN FOCUS: OBJECTIVES, REQUIREMENTS, AND THE NEW EUROPEAN CHEMICALS AGENCY

As the previous section shows, REACH is the result of a complex process, where multiple interests and players have engaged in a vigorous and heated debate over the future of EU chemicals policy. Given that REACH is still a live document and that a final regulation is expected in 2007, rather than attempting a comprehensive analysis of REACH, this section will only discuss some of its general features and central requirements, based on the Council’s Common Position and the Parliament’s first reading vote.

OBJECTIVES OF REACH

The political objectives of the proposed strategy for a future

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chemicals policy prepared by the Commission encompassed a range of important public policy goals. Pursuant to the challenge of sustainable development, and within the framework of the EC common market, REACH attempts to integrate environmental, economic, and social considerations in the design of the proposed chemicals strategy. As elaborated in the White Paper, the political objectives of REACH include:

Protection of Human Health and Promotion of a Non-toxic Environment

This objective requires a process for ensuring the safety of tens of thousands of chemicals, especially “existing” substances that have been held to a lower standard than new ones. This process would distinguish substances according to proven or suspected hazardous properties, uses, exposure, and volumes of production or trade, in order to prioritize actions. Industry, including companies along the manufacturing chain, would be responsible for generating and assessing data and assessing the risks of the use of the substances. Ultimately, this process would fill the large data gap concerning chemical hazards and uses, thereby enabling a sound chemicals policy for the protection of human health and the environment.

Maintenance and Enhancement of the Competitiveness of the EU Chemical Industry

Given the economic importance of the chemical industry in the EU, including with respect to jobs, the White Paper encouraged innovation and in particular the development of safer chemicals. In addition, a workable and realistic timetable for submission of data, coupled with flexible test data and other measures (*e.g.* testing thresholds) would limit the cost for enterprises.

Prevention of Fragmentation of the Internal Market

The White Paper places considerable importance on the internal market, following the Commission’s role as the steward of the EC market. In this light, the White Paper views health and environment protection as fully compatible with the proper functioning of the internal market in the chemicals sector, as in any other industrial sector within the Union. The White Paper also proposes that to meet its objectives, the new chemicals policy be based on full harmonization.

Increased Transparency

Transparency in the White Paper is addressed from two angles. First is the “public right to know;” that is, the public’s right to access information about the chemicals to which they are exposed. The economic implications of the public’s right to know will center on the public’s ability to make informed choices in the marketplace, avoiding dangerous products and preferring safer substitutes. The second angle relating to enhanced transparency is institutional and administrative; a single system applying to all chemicals will improve the transparency of the regulation.

Integration with International Aspects

This objective encompasses several dimensions, including recognizing test results carried out using globally harmonized

methodology in order to reduce costs and animal testing; preventing distortions to the global market by covering importers; and supporting multilateral environmental initiatives relating to chemical safety. In this latter vein, the White Paper supports efforts by the OSPAR Convention, the Stockholm Persistent Organic Pollutants Convention, and the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. This objective also addresses the need to strengthen developing countries’ capabilities and capacities for managing chemicals.

Promotion of Non-animal Testing

The White Paper recognized the difficulties and dilemmas surfacing from the need to test chemicals in different ways, including on animals, in order to assess hazard and risk. This objective seeks to reduce animal testing to an absolute minimum by maximizing the use of existing non-animal test methods. Also, this objective calls for the development of new non-animal test methods, as well as for careful definition of testing thresholds, flexible test regimes, and sequencing in the production of information.

Conformity with EU International Obligations under the WTO

The White Paper is explicit about the WTO obligations contained in the Agreement on Technical Barriers to Trade (“TBT Agreement”) (addressed below). In particular, this objective calls for preventing discrimination against imported products; ensuring that its measures are based on sound scientific evaluation of the potential threats to human health and the environment; and ensuring that its technical regulations do not create unnecessary obstacles to international trade.

The analysis of the objectives of REACH shows the close linkages between the economic, public health, and environmental dimensions of chemicals management under the broader umbrella framework of sustainable development. In this light, REACH is redefining the different roles of the various social actors involved in chemicals production and trade, and has introduced a “duty of care” approach to chemicals production and trade, where industry takes responsibility of the products that it places on the market. This duty of care is complemented by stringent requirements regarding information on chemicals, summarized by the “no data, no market” quote. REACH’s requirements also show a preference for safer substitutes (without having to fully prove dangers) as a means to gradually secure health as well as stimulate innovation. These requirements and other specific obligations contained in the REACH regulation are examined next.

REQUIREMENTS IN REACH

As a regulation, REACH is directly applicable to EU Members States and enforceable in their domestic courts. Among other things, this “harmonization” feature contrasts REACH from the current EC Directives that concern chemicals, which have been implemented by multiple and varying domestic laws in Members. Thus, REACH will ensure a common play-

ing field within the EC internal market, where all chemical producers and traders will be subject to the same specific requirements. The central requirements of REACH are found in its acronym: Registration, Evaluation, and Authorization, examined in cursory fashion below.

Registration

Registration requires a manufacturer to notify an authority of the intention to produce or import a substance and to submit a dossier containing the information required by the legislation. Registration will be obligatory for all chemicals produced or imported in volumes exceeding one ton per year, including “existing” and “new” chemicals. In general terms, unless otherwise exempted, failure to register means that the substance will not be allowed in the market.

The timing and amount of information required for registration depends partly on the volume produced or imported. While risk of a chemical substance towards human health and the environment is not necessarily proportional to the volume of production, volume is a proxy for exposure, as it allows a clear, enforceable priority setting for registration which also gives legal certainty.¹⁸ For substances above one ton, a technical dossier (containing information on the properties, uses, classification, and guidance on safe use) must be submitted to the authorities. For substances above ten tons, a chemical safety report (“CSR”) is required. A CSR documents the hazard classification of a substance and the assessment as to whether the substance is persistent, bioaccumulative and toxic (“PBT”) or very persistent and very bioaccumulative (“vPvB”). Further, the CSR also describes exposure scenarios, including appropriate risk management measures, for all identified uses of dangerous, PBT, and vPvB substances.¹⁹

REACH allows for, but does not require, chemical makers and importers to share data for registration. There are also cost-sharing provisions among registrants, designed to respect property rights to data and to fairly allocate the cost of producing the required information. New tests are only required when it is not possible to provide the information in any other permitted way, in order to minimize animal testing. In these situations, the manufacturer or importer would submit proposals for testing, which will be scrutinized by the authorities in the evaluation process before the tests are performed.

Evaluation

The evaluation process consists of an examination of the data contained in the registration dossiers provided by industry. There are two types of evaluation: dossier evaluation and sub-

stance evaluation. The dossier evaluation includes a (1) *compliance check* (or completeness check), where authorities test the registration dossiers against the registration requirements, and a (2) *checking of testing proposals*, where authorities evaluate the animal testing proposals to prevent repetition of existing tests and poor quality tests. The substance evaluation focuses on suspicions of risks to human health or the environment and may lead to requests for further information or expedited action. The new chemicals agency will develop guidance on prioritization of substances for evaluation. Evaluation may lead to the conclusion that further action needs to be explored under the authorization procedures.

Authorization

An authorization is required for the use and marketing of “substances of very high concern.” There are several categories of such substances of very high concern, constructed on the basis of their properties: (1) carcinogenic, mutagenic, or toxic for reproduction; (2) PBTs or vPvB; and (3) equivalent to the above in their potential to cause serious and irreversible effects to humans or the environment, such as endocrine disrupters. Authorization under REACH could include bans or restrictions on the manufacture or uses of these chemicals, but banning substances or uses will not occur by default. Of the estimated 30,000 produced above one ton per year, an estimated 1,500 chemicals may require authorization.

The authorization process consists of two steps. The *first step* focuses on identifying the substances that will be included in the system; the uses that will be exempted because of sufficient controls; and the deadlines that will have to be met. The new Chemicals Agency will make recommendations for priority substances for authorization based largely on risk, *i.e.* use, volume, and properties, while taking into account workability considerations. The *second step* requires industry to apply for an authorization for each use, demonstrating that either the risk of the use of the substance is adequately controlled, or that the socio-economic benefits outweigh the risks, taking account of alternative substitutes. In order to enable costs to be minimized, REACH allows groups of applications for authorization, such as by manufacturers, importers, and downstream users.

Registration, evaluation, and authorization are the supporting pillars of REACH’s new approach to chemical safety. A critical question that surfaces with respect to the operation of the proposed REACH regulation is its scope, *i.e.* which substances are covered by these requirements. In that context, it is important to note that REACH only covers substances (chemicals) but does not cover preparations. Additionally, REACH exempts

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2020 goal for a toxic-free
future.*

inter alia radioactive substances, wastes, non-isolated intermediates and substances that Member States deem necessary for their defense interests.²⁰

Yet another controversial aspect about REACH's scope is that it does not cover products.²¹ This exclusion, however, is not absolute, and REACH may apply if certain conditions are present, such as if chemicals in products are dangerous and intended to be released from the article during normal and reasonably foreseeable conditions of use. While there is considerable uncertainty in regard to the exact meaning of this language, the exclusion of products (including imported products) represents a shortcoming of the system to the extent that these products may have been manufactured utilizing dangerous chemicals that could be released unintentionally to the environment, thereby threatening public health. Further, while release may not be intended, there may be cases or products where it could nevertheless be foreseen that some of the chemicals employed in their manufacture would be released to the environment. In such cases where substances may be released incidentally to the use of the article, a simple notification is required. From another perspective, the exclusion of products from REACH means that a plethora of difficult questions concerning WTO-consistency are left for a future day.

Another key question regarding the implementation of REACH's requirements concerns the timetable for registration. REACH envisages a tiered approach for registration to be phased in over eleven years, where deadlines hinge on production volume, *e.g.* above one ton, one-hundred tons, one-thousand tons, etc. At the same time, the system is expected to be flexible enough to allow for earlier registration of substances of concern, including those having proven or suspected hazardous properties and those intended for consumer use.

It is readily apparent that the requirements in REACH are varied and complex.²² Several developing countries have commented on the difficulties that their chemical producers and exporters will face to maintain their market presence in the EC, as discussed further below. In order to facilitate the implementation of the new chemicals regulation, the creation of a new agency is envisaged, examined in turn.

A NEW EUROPEAN CHEMICALS AGENCY

In order to administer REACH and facilitate its implementation, a new European Chemicals institution is being established in Helsinki. The new Chemicals Agency is expected to build on the Commission's experience with other agencies in other fields, in particular those working on medicinal products and food safety. The agency is also expected to provide Member State authorities with technical and scientific support, as well as to coordinate the evaluation of substances by national environmental authorities. The Chemical Agency has no enforcement powers, and would rely on the Commission to enforce REACH.

A key aspect of the new European chemicals agency concerns its role with respect to information on chemicals. The central chemicals entity will manage the registration process, serving as receiving body for the registration dossiers and forwarding copies of the dossiers to the Member State authorities. The

agency will also undertake compliance checks and evaluation of testing proposals of the dossiers. The agency will maintain a comprehensive central database on all registered chemicals, performing computerized screening for properties raising particular concern. Crucially, the new agency will provide access to non-confidential information about chemicals to the general public, thereby contributing to a better understanding of chemical safety to the public worldwide.

INTERNATIONAL LAW IMPLICATIONS OF REACH

REACH's multifaceted characteristics mean that it links with various dimensions of international law. By its own nature as an EC Council Regulation, REACH is binding on EU Member States, and directly applicable before their internal courts. This argues for a detailed analysis of EU law, however, this section explores some of REACH's implications for international human rights law and trade law.

HUMAN RIGHTS AND ENVIRONMENT DIMENSION

Under human rights law, States are under an obligation to structure their legal systems in a way that ensures the free and full exercise of fundamental rights, including the right to health. In particular, international human rights law imposes upon States the duty to take concrete steps towards the full realization of the right to the highest attainable standards of physical and mental health.²³ More generally, the linkages between environmental health and human rights have been clarified by the work of UN Special Rapporteurs²⁴ and recognized by a number of international instruments.²⁵

Further, States are under a positive duty to take reasonable and appropriate measures to secure certain civil and political rights particularly affected by pollution.²⁶ The European Court of Human Rights ("ECHR") in *Fadeyeva v. Russia* observed that the State's responsibility in environmental cases may arise from a failure to regulate private industry, and inquired whether the State could reasonably be expected to act so as to prevent or put an end to the infringement of the applicant's rights.²⁷ In *Oneryildiz v. Turkey*, the Grand Chamber of the ECHR further elaborated on the positive obligation to take all appropriate steps to safeguard life, including the duty to put in place a legislative and administrative framework. In the words of the Court, "This obligation indisputably applies in the particular context of dangerous activities, where, in addition, special emphasis must be placed on regulations geared to the special features of the activity in question, particularly with regard to the level of the potential risk to human lives."²⁸

When viewed under a human rights and environment lens, REACH could represent (when completed and depending on the final outcome) a concrete step towards the realization of the right to health. This is important for the advancement of economic, social, and cultural rights, as well as for the protection of civil and political rights enshrined in the European Convention on Human Rights. In addition, in light of the persistence and long-range travel potential of certain chemicals and given the volumes of chemicals produced in the EU, REACH ultimately also contributes to improving public health and the environment

globally, and in meeting Europe's commitment to the global 2020 goal for a toxic-free future.

REACH AND THE INTERNATIONAL TRADING SYSTEM

Conformance with international trade law was an explicit consideration in the crafting of REACH. While the draft legislation was engineered by DG-Enterprise and DG-Environment, they deferred to DG-Trade on ways to steer clear of WTO violations. The treatment of substances in articles (*i.e.* chemicals in products) examined above illustrates the influence of trade law in REACH design. As noted earlier, the European Commission conducted a novel and broad Internet consultation in 2003 to hear concerns, including on trade.

On its part, the Bush administration worked with the U.S. chemical industry to undermine REACH, as a House Committee report describes.²⁹ The administration said publicly that REACH would threaten \$20 billion in U.S. chemicals exported to the EU. The House Committee report also contains references to cables sent in March 2002 and April 2003 by U.S. Secretary of State Colin Powell to U.S. trading partners in Latin America and Asia as well as Europe to oppose REACH. It may be that some of the submissions to the WTO, presented below, are the result of the U.S. campaign against REACH. Further, the U.S. Department of Commerce developed an extensive outreach plan to influence "stakeholders" within the European Union and generate opposition to REACH, and also targeted countries of the Asia-Pacific Economic Cooperation ("APEC").³⁰

In January 2004, in accordance with the WTO's TBT Agreement, the EU notified REACH to the WTO's Committee of Technical Barriers to Trade ("TBT Committee").³¹ WTO Members raised a number of issues relating to the compatibility of REACH and the TBT Agreement, including questions concerning national treatment, unnecessary obstacles to trade, international standards, and special and differentiated treatment for developing countries. Some countries also mentioned concerns with respect to intellectual property rights and the treatment of confidential information in REACH. This section provides an overview of the relevant TBT issues identified in these submissions to the TBT Committee, with a view to identifying the potential claims in a possible WTO challenge to REACH by the United States or other nations.

National Treatment

The TBT Agreement provides that the WTO Members shall ensure that their technical regulations do not accord products imported from other Members with less favorable treatment than those accorded to like products of national origin.³² WTO Members generally pointed out that REACH is more difficult for non-EU manufacturers to comply than for EU manufacturers, which leads to *de facto* discrimination.³³ Singapore elaborated on the *de facto* discriminatory effects by noting that due to long distance and unfamiliarity with REACH, non-EU producers and suppliers will face more hardship than EU producers to comply with REACH. Thailand also raised concerns about REACH's data sharing provisions (which allow the first registrant to charge 50 percent of the cost from subsequent regis-

trants),³⁴ noting that such a scheme favors EU producers because they will likely register early and then charge subsequent non-EU registrants.³⁵

Unnecessary Obstacles to International Trade

Under the TBT Agreement, technical regulations shall not be prepared, adopted, or applied to create unnecessary obstacles to international trade, and regulations shall not be more trade-restrictive than necessary to fulfill a legitimate purpose.³⁶ To some degree, every comment submitted to the TBT Committee regarding REACH raised concerns about unnecessary obstacles to international trade. The high costs associated with implementation and compliance, it was argued, would drive many competitors out of business, especially small and medium enterprises in developing countries. Some commented that the scope of REACH was broader than any OECD country, imposing administrative burdens on many substances that may pose negligible risk to health and the environment. Several countries commented that the hazard-based and volume-based approaches in REACH were incompatible with a scientific, risk-based evaluation of substances.³⁷ Finally, several WTO Members claimed that REACH did not recognize test results generated outside the EU, even where such data was obtained in conformity with the OECD Principles of Good Laboratory Practice, increasing compliance costs, frustrating cooperation, and imposing unnecessary obstacles to trade.³⁸

Relevant International Standards

The TBT Agreement requires that Members use relevant international standards that exist unless such standards would be an ineffective or inappropriate means for the fulfillment of the legitimate objectives pursued.³⁹ This provision was directly at issue in *EC – Sardines*, where the Appellate Body held that where a Member departs from a relevant international standard because it considers it to be ineffective to achieve its legitimate objectives, the burden of proof will nevertheless fall on the complaining Member.⁴⁰ It is of course open to question whether existing international standards exist to achieve the goals of REACH. Several comments charged that REACH was incompatible with international efforts to control chemicals, such as the OECD High Production Volume ("HPV") initiative or the Globally Harmonized System ("GHS") for classification and labeling.⁴¹

Special and Differential Treatment for Developing Countries

The TBT Agreement requires that in the preparation and application of technical regulations, Members take into account the special developmental, financial, and trade needs of developing country Members, with a view to ensuring that such technical regulations, standards, and conformity assessment procedures do not create unnecessary obstacles to exports from those Members.⁴² Interpreting a similarly worded provision in the WTO Agreement on Sanitary and Phytosanitary Measures, the *EC-Biotech* Panel noted that "taking into account" does not prescribe a specific result to be achieved, and that in weighing and balancing the various interests at stake, the needs of a develop-

ing country did not have priority over, for instance, other legitimate interests.⁴³ The TBT Agreement also provides that the Member imposing technical regulations shall take reasonable measures to arrange for the regulatory bodies to advise other members, grant them technical assistance on mutually agreed terms and conditions.⁴⁴

Brazil, China, Cuba, and Thailand raised particular concerns about REACH and these provisions of the TBT Agreement, noting that advice and technical assistance were necessary, including by way of implementation guidance by sectors.⁴⁵

NEXT STEPS

At the time of writing, the Council has been discussing the Parliament's November 17, 2005 vote. The Council struck a political agreement on Dec. 13, 2005 under the UK Presidency. A Common Position was approved in February 2006 reflecting some of the Parliament's first reading. The Parliament will take up the Council's draft in second reading in May or June 2006. The Parliament can then either accept the Council's amendments or pass certain amendments for consideration in the formal conciliation process. In the international

sphere, the comments submitted to the TBT Committee may prelude a brewing trade challenge to certain measures adopted pursuant to REACH.

CONCLUSION

REACH is coming. After years of dialogue, debate and bruising politics, the EU has created a new model for regulating chemicals. Did the EU over-reach? Will the final compromises so weaken the system that few health benefits will result? Will REACH lead the world toward greener chemistry or burden EU producers and outsource pollution elsewhere?

REACH is motivated by a desire to eliminate substances that negatively impact on human health and its underlying determinants, including the environment. But this first requires an adequate understanding of the basic characteristics of chemicals – something that is impossible with the current level of knowledge and built-in incentives. By ensuring that much of this information on chemicals will be made publicly available, it is likely that governments, companies, and civil society beyond the EU will benefit as well.



ENDNOTES: Europe's REACH

¹ Inger Schörling, REACH - The Only Planet Guide to the Secrets of Chemicals Policy in the EU. What Happened and Why? (Greens/ European Free Alliance in the European Parliament, Brussels) April 2004.

² Commission of the European Communities, White Paper: Strategy for a Future Chemicals Policy, at 6, COM(2001) 88 final, Feb. 27, 2001 [hereinafter White Paper].

³ It is important to distinguish "chemicals policy" (which focuses generally on what substances are allowed in commerce) from traditional pollution issues (which concern how to manage wastes, emissions, discharges, etc.).

⁴ See *infra*, Evolution of EU Chemicals Policy.

⁵ See Schörling, *supra* note 1.

⁶ Dir 67/548/EEC.

⁷ Dir 76/769/EEC.

⁸ See *infra*, Roots of the Problem: Piecemeal Approaches to Chemicals Management.

⁹ Dir 88/379/EEC.

¹⁰ Norway Ministry of the Environment, Esbjerg Declaration, available at <http://www.dep.no/md/nsc/declaration/022001-990243/dok-bn.html> (last visited Apr. 17, 2006).

¹¹ See generally, UNEP Strategic Approach to International Chemicals Management, <http://www.chem.unep.ch/saicm> (last visited Apr. 17, 2006).

¹² The 1992 Convention for the Protection of the Marine Environment of the North-East Atlantic (the "OSPAR Convention") replaced the Oslo and Paris Conventions as between the Contracting Parties (art. 31). "Oslo Convention" means the *Convention for the Prevention of Marine Pollution by Dumping from Ships and Aircraft* signed in Oslo on Feb. 15, 1972, as amended by the protocols of Mar. 2, 1983 and Dec. 5, 1989.

"Paris Convention" means the Convention for the Prevention of Marine Pollution from Land-based Sources, signed in Paris on June 4, 1974, as amended by the protocol of Mar. 26, 1986.

¹³ Annual Report of the OSPAR Commission, 2002 - 2003, vol. 1, chp. 4, ¶ 75-76.

¹⁴ See European Commission website, "REACH," <http://europa.eu.int/comm/environment/chemicals/reach.htm> (last visited Apr. 17, 2006).

¹⁵ Currently there are 732 Members of the European Parliament after accession of ten new Member States. See generally, European Parliament website, "How Parliament is Organised," <http://www.europarl.eu.int/parliament/public/staticDisplay.do?language=EN&id=45> (last visited Apr. 17, 2006).

¹⁶ See generally, The Council of the European Union website, <http://ue.eu.int/showPage.ASP?lang=en> (last visited Apr. 17, 2006).

¹⁷ For a detailed explanation of the co-decision process, see Co-Decision Guide, available at http://ue.eu.int/uedocs/cms_data/docs/2004/4/29/Codecision%20guide.pdf (last visited Apr. 17, 2006).

¹⁸ See European Commission, Q&A on REACH, Mar. 23, 2006, at 14. (The tonnage-triggered system for registration is based on a trade-off between workability and the need to cover all substances, at 24).

¹⁹ European Commission, REACH in Brief, Sept. 15, 2004, at 5. (Exposure scenarios are sets of conditions that describe how substances are manufactured or used during their life-cycle and how the manufacturer or importer controls, or recommends to control exposures of humans and the environment.)

²⁰ See Q&A on REACH, *supra* note 18, at 4.

²¹ See Q&A on REACH, *supra* note 18, at 16-17; see generally, Trans Atlantic Consumer Dialogue, Briefing Paper on REACH, Doc No. Trade - 14pp-04 (June 2004), at 4.

²² Other aspects of REACH not mentioned or elaborated here include, inter alia, classification and labeling, decision-making procedures, and downstream users.

²³ International Covenant on Economic, Social, and Cultural Rights ("ESCR"), entered into force January 3, 1976, Art. 2.1 and 12, 993 U.N.T.S. 3.; see also, World Conference on Human Rights, Vienna, 14-25 June 1993, Vienna Declaration and Programme of Action, 12 July 1993, A/CONF.157/23; World Health Organization, Health and Human Rights, July 2002; see generally, Sofia Gruskin & Daniel Tarantola, Health and Human Rights, The Oxford Textbook of Public Health (Detels et al. eds., 4th ed. 2004).

²⁴ See generally, Review of Further Developments in Fields with Which

the Sub-Commission Has Been Concerned, Human Rights and the Environment, Final Report Prepared by Mrs. Fatma Zohra Ksentini, Special Rapporteur, U.N. Doc. E/CN.4/Sub.2/1994/9 (1994); Paul Hunt, Report of the Special Rapporteur: The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, U.N. Doc. E/CN.4/2003/58 (2003); Adverse Effects of the Illicit Movement and Dumping of Toxic and Dangerous Products and Wastes on the Enjoyment of Human Rights, Report Submitted by the Special Rapporteur on Toxic Waste, Mrs. Fatma-Zohra Ouhachi-Vesely, U.N. Doc. E/CN.4/2000/50 (2000).

²⁵ E.S.C. Res. 71, U.N. ESCOR Hum. Rts. Comm., 59th Sess. at 16-17, U.N. Doc. E/CN.4/2003/L.11/Add.7 (2003).

²⁶ See *Powell & Rayner v. United Kingdom*, 172 Eur. Ct. H.R. (ser. A) (1990), at ¶ 41; *Guerra and others v. Italy*, 26 Eur. Ct. H.R. 357 (1998), at ¶ 58; *Taskin and others v. Turkey*, Eur. Ct. H.R., Nov. 10, 2004, ¶ 113, available at <http://www.echr.coe.int/echr> (last visited Apr. 17, 2006).

²⁷ *Fadeyeva v. Russia*, Eur. Ct. H.R., June 9, 2005, at ¶ 89, available at <http://www.echr.coe.int/echr>.

²⁸ *Oneryildiz v. Turkey*, 39 Eur. H.R. Rep 12 (2004), at ¶¶ 89, 90.

²⁹ U.S. House of Representatives, Committee on Government Reform, Special Investigation Division, A special Interest Case Study: The Chemical Industry, The Bush Administration, and European Efforts to Regulate Chemicals, (Apr. 1, 2004). See also, Elizabeth Becker, *White House Undermined Chemical Tests, Report Says*, N.Y. TIMES, Apr. 2, 2004, at C2.

³⁰ U.S. House of Representatives, *id.* at 13. (The Commerce Department Report (Feb. 18, 2003) “notes that Mexico and Japan had expressed concern about REACH to the European Union. The Commerce Department report states: “We will be encouraging other delegations here to do likewise.”)

³¹ See Notification G/TBT/N/EEC/52.

³² World Trade Organization, Agreement on Technical Barriers to Trade, art. 2.1, available at http://www.wto.org/English/docs_e/legal_e/17-tbt.pdf (last visited Apr. 17, 2006) [hereinafter TBT Agreement].

³³ See Submissions to the TBT Committee concerning REACH regarding Taiwan & Japan.

³⁴ See Submissions to the TBT Committee concerning REACH regarding Thailand ¶ 3.6.

³⁵ See Submissions regarding Thailand, *id.*

³⁶ TBT Agreement, *supra* note 32, at art. 2.1.

³⁷ Submissions to the TBT Committee concerning REACH regarding Brazil ¶ 6, Taiwan, Chile, United States ¶ 17, China ¶ 6.

³⁸ Submissions to the TBT Committee concerning REACH regarding Japan III.2. Brazil ¶ 3, Australia, Canada, USA ¶¶ 36-37.

³⁹ TBT Agreement, *supra* note 32, at art. 2.4.

⁴⁰ EC- Trade Description of Sardines, Report of the Appellate Body, WT/DS231/AB/R, (26 September 2002), ¶¶ 275, 282.

⁴¹ Submissions to the TBT Committee concerning REACH regarding Brazil ¶ 3, Thailand ¶ 5, Canada, China ¶ 6.

⁴² TBT Agreement, *supra* note 32, at art. 12.3.

⁴³ EC-Biotech, Interim Panel Report, WT/DS291/, WT/DS292/, WT/DS293/, ¶¶ 7.16, 13-4.

⁴⁴ TBT Agreement, *supra* note 32, at art. 11.3.

⁴⁵ Submissions to the TBT Committee concerning REACH regarding Brazil ¶ 3, China ¶ 9, Thailand ¶ 5.